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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,537	02/08/2002	Kevin B. Morton	NEOMTRX.4C1DV1	4244

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EXAMINER

FOREMAN, JONATHAN M

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 08/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/072,537

Applicant(s)

MORTON ET AL.

Examiner

Jonathan ML Foreman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2004.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-16,18-30 and 34-64 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-7,9-11,16,18,26,29,30,34,35,36,44,52,53,57 and 60-64 is/are rejected.
- 7) ☒ Claim(s) 8,12-15,19-25,27,28,37-43,45-51,54-56,58 and 59 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

New grounds of rejection are contained within this Office Action. Accordingly this action has been made Non-Final.

#### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 60 – 62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Claims 60 - 62 recite the limitations "the proximal cap" and "the retention structure". There is insufficient antecedent basis for these limitations in the claims.

#### *Claim Rejections - 35 USC § 102*

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 3, 57 and 63 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S Patent Application Publication No. 2001/0031911 to Khouri.

In regards to claims 1, 3, 57 and 63, Khouri discloses an adjustable support defining a concavity, the support comprising a plurality of petals (12) movable through an adjustment range as

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a result of the hinge (42) [0038]; an inflatable bladder (62) within the concavity; and a vacuum source in communication with the concavity [0040]. Khouri discloses a disposable patient interface (61) [0040] and a central processing unit for controlling the inflatable bladder (26).

6. Claims 34 and 44 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication No. 2003/0004459 to McKendry et al.

In regards to claims 34 and 44, McKendry et al. discloses a device (Figure 2, 4) for obtaining a sample from a breast [0013] including a frame (26); at least one support (54) on the frame having a side for facing in the direction of a patient when in use; a moveable wall (56) positioned between the support (54) and the patient while in use; and a disposable patient interface (58) positioned between the movable wall (56) and the patient, for contacting the patient when in use, the patient interface (58) including a flexible membrane comprising a low durometer thermoplastic elastomer [0016] having a tubular body (74) with a proximal end (68) having a first diameter and a second end (63) having a second larger diameter, and a releasable connector on the proximal end [0043].

7. Claims 1, 9 – 11, 52, 53, 63 and 64 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,607,495 to Skalak et al.

In regards to claims 1, 9 – 11, 52, 53, 63 and 64, Skalak et al. discloses adjustable support defining a concavity (Col. 8, lines 8 – 14), the support comprising a plurality of petals (61) movable through an adjustment range (Col. 7, lines 41 – 56); an inflatable bladder (20) within the concavity; and a vacuum source in communication with the concavity (Col. 9, lines 3 – 7). A central processing unit inflates and deflates the bladder in accordance with a predetermined program alternating between inflation and deflation cycles (Col. 8, lines 22 – 39). The program performs the cycles within the range of from about 2 to about 40 cycles per minute (Col. 9, lines 12 – 14). The bladder has an inflated thickness of no more than about 0.5 inches (Col. 13, line 19).

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 16, 18, 26 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,575,768 to Lockridge et al. in view of U.S. Patent No. 6,579,258 to Atkin et al.

In regards to claims 16, 18, 26 and 29, Lockridge et al. discloses a device for obtaining an intraductal fluid sample from a breast (Col. 2, line 63 – 65) including a frame (12); at least three moveable supports (1408; Col. 4, lines 30 – 31) on the frame; and a moveable wall (1400) positioned between the supports and the patient. However, Lockridge et al. fails to disclose a disposable patient interface comprising a flexible membrane being positioned between the moveable wall and the patient. Atkin et al. discloses a device for obtaining an intraductal fluid sample from a breast including a disposable patient interface (5) comprising a flexible membrane (Col. 3, lines 29- 40). It would have been obvious to one having ordinary skill in the art at the time the invention was made to include a disposable interface as taught by Atkin et al. to the device as disclosed by Lockridge et al. in order to apply a gentle pressure to the areola on the breast and nipple in a peristaltic way to encourage lactation (Col. 4, lines 62 – 67). The selection of a known material based upon its suitability for the intended use is a design consideration within the skill of the art. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960). In the present case it would have been obvious to one having ordinary skill in the art to form the disposable interface of a low durometer thermoplastic elastomer or any flexible material as desired.

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10. Claims 34, 35, 36 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,575,768 to Lockridge et al. in view of U.S. Patent Application Publication No. 2003/0004459 to McKendry et al.

In regards to claims 34, 35, 36 and 44, Lockridge et al. discloses a device for obtaining an intraductal fluid sample from a breast (Col. 2, line 63 – 65) including a frame (12); at least three moveable supports (1408; Col. 4, lines 30 – 31) on the frame; and a moveable wall (1400) positioned between the supports and the patient. However, Lockridge et al. fails to disclose a disposable patient interface comprising a flexible membrane being positioned between the moveable wall and the patient and having a tubular body with a proximal end having a first diameter and a second end having a second, larger diameter, and a releasable connector on the proximal end. McKendry et al. discloses a device (Figure 2, 4) for obtaining a sample from a breast [0013] including and a disposable patient interface (58) positioned between the movable wall (56) and the patient, for contacting the patient when in use, the patient interface (58) including a flexible membrane comprising a low durometer thermoplastic elastomer [0016] having a tubular body (74) with a proximal end (68) having a first diameter and a second end (63) having a second larger diameter, and a releasable connector on the proximal end [0043]. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include a disposable interface as taught by McKendry et al. to the device as disclosed by Lockridge et al. in order to collapse around the breast to establish the vacuum (Abstract, lines 5 – 6).

11. Claims 4 – 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2001/0031911 to Khouri as applied to claim 1 above and further in view of U.S. Patent No. 6,358,226 to Ryan.

In regards to claims 4 – 7, Khouri discloses a device having a fluid circulation pathway for circulating fluid through an inflatable bladders, but fails to disclose a heat source in thermally conductive contact with the fluid to heat the bladders. Ryan discloses a device (Figure 1) having a heat source in thermally conductive contact with the fluid of an inflatable bladder (Co. 4, lines 27 – 49). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as disclosed by Khouri to include a heat source in thermally conductive contact with the fluid as taught by Ryan in order to make the user of the device more comfortable.

12. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,575,768 to Lockridge et al. in view of U.S. Patent No. 6,579,258 to Atkin et al. as applied to claim 16 above and further in view of U.S. Patent No. 6,358,226 to Ryan.

In regards to claim 30, Lockridge et al. in view of Atkin et al. discloses a device for obtaining an intraductal fluid sample from a breast but fails to disclose a heat source in thermal communication with the movable wall. Ryan discloses device for obtaining an intraductal fluid sample from a breast (Figure 1) having a heat source in thermally conductive contact with a movable wall (Co. 4, lines 27 – 49). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as disclosed by Lockridge et al. in view of Atkin et al. to include a heat source in thermally conductive contact with the movable wall as taught by Ryan to raise the mammary gland to a temperature that makes milk withdrawal more comfortable (See Abstract).

### ***Response to Arguments***

13. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

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*Allowable Subject Matter*

14. Claims 8, 12 – 15, 19 – 25, 27, 28, 37 – 43, 45 – 51, 54 – 56, 58 and 59 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

15. Claims 60 - 62 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

*Conclusion*

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent No. 3,995,621 to Fletcher et al.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (703) 305-5390. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703)308-3130. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



JMLF  
August 20, 2004



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